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SCHMEISER OLSEN & WATTS
18 E UNIVERSITY DRIVE
SUITE # 101
MESA, AZ 85201

EXAMINER

BHATNAGAR, ANAND P

ART UNIT PAPER NUMBER

2623

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,346

Applicant(s)

WALLACE ET AL.

Examiner

Anand Bhatnagar

Art Unit

2623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2 and 3</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because the word "Houndsfield " in the specifications is misspelled because there is no "d" in the correct spelling and should be "Hounsfield." Correction is required. See MPEP § 608.01(b).

Claim Objections

2. Claims 3 and 23 are objected to because of the following informalities:
The word "Houndsfield " is misspelled because there is no "d" in the correct spelling and should be "Hounsfield." Appropriate correction is required.

Claims 32-38 are objected to. These claims are method claims but come off of claim 30 which is an apparatus claim which is improper dependency. Examiner will address these claims as best understood. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 2623

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Ostuni (U.S. patent 5,937,083).

Regarding claim 1: An apparatus comprising:

a medical image data file, the medical image data comprised of voxels, each voxel corresponding to an intensity value at a location within an image (fig. 1 element 108, col. 4 lines 7-13, and col. 6 lines 26-30, wherein the images and intensity data of the voxels is stored in a memory, #108, from which the gradient data is determined. The images of a patient being stored in the memory is read as a medical image data file since data that is stored in most memories is stored as a file.);

a processor (fig. 1 element 116);

a memory coupled to the processor (fig. 1 element 112 and col. 6 lines 23-25);

an image data transformation mechanism residing in the memory (fig. 1 elements 110 and 112 and col. 6 lines 23-25, wherein the image transformation matrix is stored in the memory, #112), the image data transformation mechanism transforming the medical image data (col. 6 lines 23-25 and 45-49, wherein the transformation parameters are applied to an image which transforms the image in the 3D space);

calculating a gradient between voxels in the medical image data to create gradient data (col. 4 lines 6-14, wherein the voxel values of the image(s) is obtained);

rectifying the gradient data to create interface data (col. 4 lines 21-35, wherein the gradient values of the voxels are thresholded. This thresholding is read as "rectifying" the gradient data. Once the gradient data is thresholded the values above the threshold are given a value of one and values below the threshold is given a value of zero. This process is read as creating a interface data (binary image data of ones and zeros) obtained from thresholding the gradient data, read as rectifying the gradient data.); and

displaying the interface data as output (fig. 1 element 116 and 118 and col. 6 lines 26-30, wherein the interface data, the binary ones and zeros, is output and displayed on the display, #118).

Regarding claim 2: The apparatus wherein the image data transformation mechanism further comprises a filter to filter the interface data to remove spurious interface data (col. 7 lines 16-18, wherein the unwanted voxels are filtered out by thresholding the voxels).

Regarding claim 4: The apparatus wherein the output comprises an Interface Plot wherein said Interface Plot is an image of interface data which illustrates gradient features in the medical image data (fig. 1 element 118, wherein the image displayed is of the interface data that was created from the gradient data).

Regarding claim 5: The apparatus according further comprising an image generating device to generate the medical image data file (fig. 1 elements 104, 106, and 108, wherein the data obtained is processed into image data and stored in an image memory, #108. This storage of data is read as a file being created to store the data in a specific area of the memory).

Regarding claim 31: It is rejected for the combination of reasons of claims 1 and 2 above.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A.) Claims 3, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostuni (U.S. patent 5,937,083).

Regarding claim 3: The apparatus according wherein each voxel is an intensity in Hounsfield Units. Examiner takes Official Notice. Computerized tomography intensity data is in Hounsfield units as admitted by the applicant on top of page 9 of the specifications of applicant's instant invention.

Regarding claim 6: The apparatus wherein the medical image generating device is a CT scanner.

Ostuni discloses to perform gradient analysis on MRI medical images. Ostuni further discloses that the process can be performed on other data which is not MRI data (col. 11 lines 66-67). Ostuni does not teach to obtain images using a CT scanner. It would have been obvious to one skilled in the art to substitute the MRI image data with any other similar medical imaging data such as obtained by CT scanner, PET, x-ray, etc.

Regarding claim 7: The apparatus wherein the medical image data file comprises a CT scan of a brain. It is rejected for the same reason as claim 6 above and for Ostuni teaching the MRI imaging of the brain (fig. 4a-d and col. 9 lines 53-60).

B.) Claims 8-30, 32, 33, and 34-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostuni (U.S. patent 5,937,083) and Gosche (U.S. patent 6,430,430 B1).

Regarding claim 8: The apparatus further comprising an image analysis mechanism residing in memory wherein the image analysis mechanism renders an output comprising a diagnostic indication of brain pathology.

Ostuni discloses to perform gradient analysis on MRI images of the brain. Ostuni does not teach to perform analysis on the brain images for any abnormalities/pathologies. Gosche teaches an automated medical image analysis system which detects for presence of many brain pathologies (col. 1 lines 17-26). It would have been obvious to one skilled in the to combine the

teaching of Gosche to that of Ostuni because they are analogous in analyzing voxel intensity gradients in medical images (Gosche; col. 10 lines 50-53). One in the art would have been motivated to incorporate the brain pathology analysis system of Gosche to that of Ostuni to determine changes in the brain structure in order to diagnose pathologies such as volume changes, Alzheimer's disease, etc. (Gosche; abstract and col. 9 lines 7-13). Since the system is an automated brain pathology detection system an indication of the pathology found is given (col. 9 lines 20-25, wherein the system helps in diagnosing a disease).

Regarding claim 9: The apparatus wherein the image analysis mechanism comprises a free blood detection mechanism to detect the presence of intensity readings within the medical image data which indicates the presence of acute free blood in the brain.

Ostuni, as modified by Gosche, teaches to diagnose pathologies (such as volume changes, tumor mass, Alzheimer's disease, etc.) in the brain by gradient image analysis. Ostuni, as modified by Gosche, does not teach to diagnose free blood in the brain. It would have been obvious to one skilled in the art to modify the brain pathology diagnosis system of Ostuni, as modified by Gosche, to include a free blood diagnosis, edema, tumor, etc. steps in order to look for other brain pathologies that may be present in the brain.

Regarding claim 10: The apparatus wherein the image analysis mechanism comprises a mass detection mechanism to detect the presence of

gradient data which defines an enclosed structure indicative of a mass in the brain.

Ostuni, as modified by Gosche, teaches to diagnose pathologies (such as volume changes, tumor mass, Alzheimer's disease, etc.) in the brain by gradient image analysis. Ostuni, as modified by Gosche, does not teach to diagnose free blood in the brain. It would have been obvious to one skilled in the art to modify the brain pathology diagnosis system of Ostuni, as modified by Gosche, to include a free blood diagnosis, edema, tumor, etc. steps in order to look for other brain pathologies that may be present in the brain.

Regarding claim 11: The apparatus wherein the image analysis mechanism comprises an edema detection mechanism to detect the presence of a decrease in gradient at a neuroanatomical region compared to the gradient measured in the corresponding region in the opposite hemisphere of the brain.

Ostuni, as modified by Gosche, teaches to diagnose pathologies (such as volume changes, tumor mass, Alzheimer's disease, etc.) in the brain by gradient image analysis. Ostuni, as modified by Gosche, does not teach to diagnose free blood in the brain. It would have been obvious to one skilled in the art to modify the brain pathology diagnosis system of Ostuni, as modified by Gosche, to include a free blood diagnosis, edema, tumor, etc. steps in order to look for other brain pathologies that may be present in the brain. Further, it is obvious to one skilled in the art to look and compare both hemispheres of the brain to look for certain brain pathologies that may exist in any of the two hemispheres.

Regarding claim 12: The apparatus of Claim 11 wherein the neuroanatomical region is one of the insular stripe, the interface between the caudate nucleus and the anterior horn of the lateral ventricle, and the cortical grey/white interface.

Ostuni, as modified by Gosche, teaches to look at different regions of the brain such as the thalamus, the ventricles, caudate nucleus, white and gray areas, etc. Ostuni, as modified by Gosche, does not teach to look at the insular stripe. It would have been obvious to one skilled in the art to modify the system to include this region in order to use it for identifying other structures near it or for looking for pathologies in or near this area.

Regarding claim 13: The apparatus wherein the image analysis mechanism comprises an evaluation mechanism (Gosche; col. 9 lines 19-26, wherein the disease/pathology is diagnosed and the severity of it determined).

Regarding claim 14: The apparatus of Claim 9 wherein the medical image data file comprises a CT scan of a brain and wherein the image data transformation mechanism displays the interface data as an Interface Plot illustrating gradient structures in corresponding locations in the brain (Ostuni; fig. 1 element 118, wherein the image displayed is of the interface data that was created from the gradient data).

Regarding claim 15: It is rejected for the combination of rejections of claims 1 and 8 above.

Regarding claim 16: The apparatus wherein the output comprises an Interface Plot wherein said Interface Plot is an image of the filtered interface matrix which illustrates gradient features in the brain image matrix data (fig. 1 element 118, wherein the image displayed is of the interface data that was created from the gradient data).

Regarding claim 17: The apparatus further comprising an image generating device to generate the brain image matrix data. It is rejected for the same reason as claim 5 above.

Regarding claim 18: The apparatus wherein the image generating device is a CT scanner. It is rejected for the same reason as claim 6 above.

Regarding claim 19: The apparatus further comprising an image analysis mechanism residing in memory wherein the image analysis mechanism renders an output comprising a diagnostic indication of brain pathology. It is rejected for the same reason as claim 8 above.

Regarding claim 20: The apparatus wherein the image analysis mechanism comprises a free blood detection mechanism to detect the presence of intensity readings within the medical image data which indicates the presence of acute free blood in the brain. It is rejected for the same reason as claim 9 above.

Regarding claim 21: The apparatus wherein the image analysis mechanism comprises an edema detection mechanism to detect the presence of a decrease in gradient in the neuroanatomical region compared to the gradient

measured in the corresponding region in the opposite hemisphere of the brain. It is rejected for the same reason as claim 11 above.

Regarding claim 22: The apparatus wherein the neuroanatomical region is one of the insular stripe, the interface between the caudate nucleus and the anterior horn of the lateral ventricle, and the cortical grey/white interface. It is rejected for the same reason as claim 12 above.

Regarding claim 23: It is rejected for the combination of reasons of claims 1 and 3 above.

Regarding claim 24: The program product wherein the output comprises an Interface Plot. See claim 4 above.

Regarding claim 25: The program product wherein the brain image data comprises data from an image generating device. See claim 5 above.

Regarding claim 26: The program product wherein the image generating device is a CT scanner. See claim 6 above.

Regarding claim 27: The apparatus further comprising an image analysis mechanism residing in memory which renders an output comprising a diagnostic indication of brain pathology. See claim 8 above.

Regarding claim 28: The apparatus wherein the image analysis mechanism comprises a free blood detection mechanism to detect the presence of free blood in the brain. See claim 9 above.

Regarding claim 29: The apparatus wherein the image analysis mechanism comprises an edema detection mechanism to detect the presence of

a decrease in gradient at a neuroanatomical region compared to the gradient measured in the corresponding region in the opposite hemisphere of the brain.

See claim 11 above.

Regarding claim 30: The apparatus wherein the neuroanatomical region is one of the insular stripe, the interface between the caudate nucleus and the anterior horn of the lateral ventricle, and the cortical grey/white interface. See claim 12 above.

Regarding claim 32: The method wherein the output comprises an Interface Plot. See claim 1 above.

Regarding claim 33: The method further comprising an image generating device. See claim 5 above.

Regarding claim 34: The method wherein the image generating device is a CT scanner. See claim 6 above.

Regarding claim 35: The method further comprising an image analysis mechanism which renders an output comprising a diagnostic indication of brain pathology. See claim 8 above.

Regarding claim 36: The method wherein the image analysis mechanism comprises a free blood detection mechanism to detect the presence of acute free blood in the brain. See claim 9 above.

Regarding claim 37: The method of Claim 35 wherein the image analysis mechanism comprises an ischemic injury detection mechanism to detect the presence of a decrease in gradient at a neuroanatomical region compared to the

gradient measured in the corresponding neuroanatomical region in the opposite hemisphere of the brain. Examiner takes official notice because it is well known in the art to look for ischemic injury in the brain in CT images. See claim 11 for analyzing the two hemispheres.

Regarding claim 38: The method of Claim 37 wherein the neuroanatomical region is one of the insular stripe, the interface between the caudate nucleus and the anterior horn of the lateral ventricle, and the cortical grey/white interface. See claim 12 above.

Regarding claim 39: It is rejected for the combination of reasons of claims 1, 6, and 11 above.

Regarding claim 40: It is rejected for the combination of reasons of claims 1, 8, 9, 10, and 11 and for the limitation of: analyzing the brain image to find sulcal effacement (Gosche; col. 9 lines 65-67 and col. 10 lines 1-11, wherein the volume of the brain structures is determined, i.e. changes, such as sulcal effacement, in the brain structures will obviously be obtained in the volume analysis).

Regarding claims 41 and 42: The method further comprising obtaining and analyzing patient information. Examiner takes official notice.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

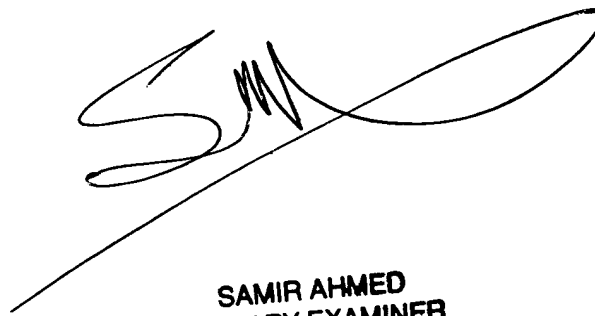
Tsuda (U.S. patent 5,842,980) for a MRI inspecting system.

Tannenbaum et al. (U.S. patent 6,535,623 B1) for a cardiac analysis system.

Contact Information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand Bhatnagar whose telephone number is (703) 306-5914, whose supervisor is Amelia Au whose number is 703-308-6604, group fax is 703-872-9306, and Tech center 2600 customer service office number is 703-306-0377.

AB



**SAMIR AHMED
PRIMARY EXAMINER**

Anand Bhatnagar

Art Unit 2623

July 14, 2004